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INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 : A61F 2/24 // A61B 17/00, 19/02	A1	(11) International Publication Number: WO 95/17139
		(43) International Publication Date: 29 June 1995 (29.06.95)

(21) International Application Number: PCT/SE94/01247

(22) International Filing Date: 22 December 1994 (22.12.94)

(30) Priority Data:

9304234-9	22 December 1993 (22.12.93)	SE
9403043-4	13 September 1994 (13.09.94)	SE

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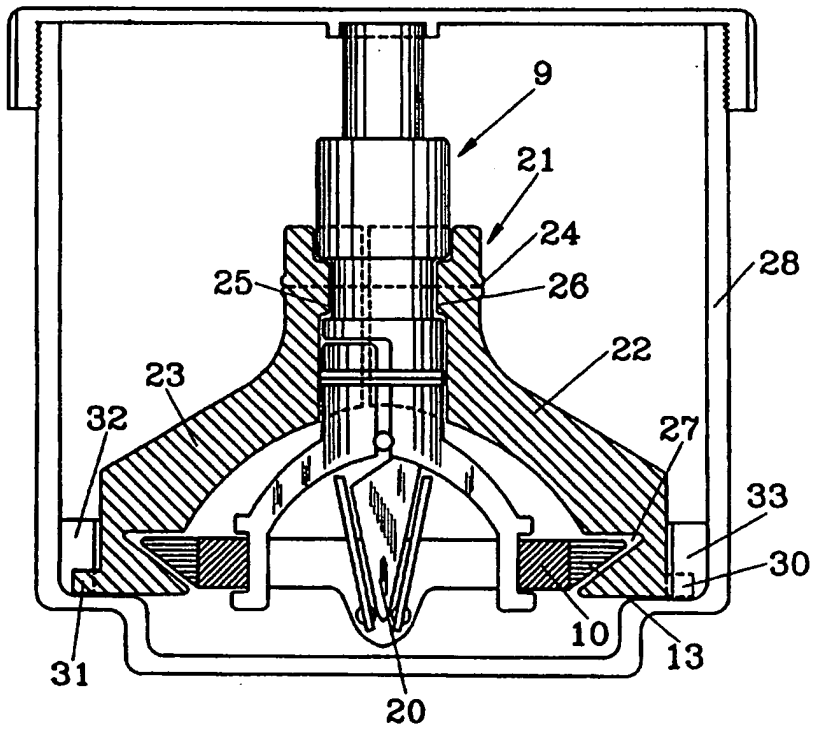
(81) Designated States: CA, JP, US, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).

Published
With international search report.
In English translation (filed in Swedish).

(54) Title: CARDIAC VALVE HOLDERS

(57) Abstract

A holder (9) for artificial heart valves (10-13), of the type that is firmly fixed to the valve, which is intended to be removed first after that the valve is correctly placed or operated inside, by breaking a transportation safety (17) is broken, after which the holder can be removed. The holder (9) is equipped with safety means (20) extending into the heart valve (10-13), which is formed to fit only into a certain definite valve type, valve position and valve size.



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CARDIAC VALVE HOLDERS

The present invention refers to a holder for artificial heart valves, of the type which is firmly but detachably attached to the valve and which is intended to be removed first after that the valve is correctly placed or operated inside, by braking a transportation safety whereby the partial foldable holder can be removed.

BACKGROUND OF THE INVENTION

Within the cardiac surgery the implantation of artificial heart valves cover about 20% of operations. Considering the entire world, this implies implantation of at least 100000 valves per year.

Heart valves are supplied in different sizes from factories in small transportation containers. For each product there is a prosthesis tester to measure which size to fit into the actual heart. When the test is finished, the actual size and type of valves are produced and the implantation is carried out.

The holder for artificial heart valves is found for mechanical valves and for biological valves. The purpose of the holder is to:

1) fixe the valve in its container during the transportation, and

2) serve as a handle for a cardiac surgeon and his operation team during the implantation.

There are two main types of valves: a) aortic valves and b) mitral valves. Moreover, these are produced in several different sizes.

If wrong size or type of valve is used, results can be disastrous, therefore the identification of the valves are surrounded by security procedures at the operation time.

It is consequently very important that the valves, which are much alike, are implanted in the heart in correct way and in correct position, since an incorrectly placed valve can cause death of the patient. Therefore aortic valves and mitral valves should not be allowed to be mixed, which can happen in several ways. A method is to implant a mitral valve in aortic position, or the aortic valve in mitral position. Another method is to implant a valve turned wrong way (up and down), which is possible in both positions.

Another type of error that can occur is wrong packing of the product at the factory. Usually, there is an adhesive label on the transport can, which indicates the content. At the factory the packaging is surrounded by several security routines to ensure that the content of the container corresponds to the text, which the adhesive label on the container indicates. Despite this, wrong packaging occurs as well. For example, a valve of size 25 can be put in a container with size indication 27 and an operative mistake can be the consequence, if the mistake is not detected through the control at the operation theatre.

Another problem with operation of the heart valve is that

the holder or the prosthesis tester breaks down and fragments of these have been dropped and are left inside the heart. Also, it has occurred that the entire holder has been forgotten in the heart, believing that it is a part of the heart valve.

THE OBJECTS OF THE INVENTION AND MOST IMPORTANT FEATURES

The object of the present invention is to provide a holder for the heart valve that as much as possible eliminates or reduces such mistakes as mentioned above. Another object of the invention is to prevent the wrong packaging of the valves provided with the holder already at the production stage, and a third object is to be able to detect a holder or a part thereof, which during the operation could have been dropped. These tasks have been solved through the features stated in the claims.

DESCRIPTION OF THE DRAWINGS

The invention will be described closer below using some embodiments, with reference to attached drawings.

Fig. 1 schematically shows, in a supernatural size, a cut through a conventional standard holder mounted in an artificial aortic valve.

Fig. 2 shows a cut, analogous to fig. 1, through a holder with a heart valve for aortic position according to the present invention.

Fig. 3 shows a cut through a conventional standard holder for a mitral valve.

Fig.4 shows a cut, analogous to fig. 3, through a holder with a heart valve for mitral position according to the present invention placed in a transportation container.

Fig. 5 shows a cut through a holder with heart valve according to a modified embodiment, which is provided with a safety ring and placed in a transportation container.

Fig. 6 shows a holder according to figure 2 with an aortic prosthesis rigidly sewn to the heart valve.

Fig. 7 shows a holder for a biological heart valve in the aortic position.

DESCRIPTION OF THE EMBODIMENTS

The invention is exemplified below for mechanical valves of double blade type, but same principles can of course be applied to any type of valve holders.

The heart valve itself consists of a valve ring 10, in which two semicircular valve blades 11 are mounted, each on a joint axis 12. Exterior to the valve ring 10 there is a valve cuff 13, which is the 'soft' part of the valve, which is sewn firmly (sutured) on the heart.

A valve holder 9 in this example consists of two parts 14 and 15, which are mutually united through a joint 16. The holder 9 is mounted on the valve ring 10 with the valve blade in an open position and after mounting the two parts are held together by a suture 17 around the two handle portions 18,19 of the holder. To be able to remove the holder from the valve, suture 17 is cut and the holder is opened inwardly through the joint 16.

As it appears from fig. 2 safety means 20 is provided by means of an extension of the handle portion 19, which continues downwards between two blades 11 of the heart valve in the aortic case, (Fig. 2), and along one side of a blade 11 in the mitral case (Fig. 4) respectively.

Preferably, the holder 9 for the aortic and mitral valves, is provided with different colours or colour codes, e.g. red for aortic holder and blue for a mitral holder. This will be very clear indication for person who handles the valve, who is informed about the holder in question. If the person in question is colour-blind or do not know the colour coding, the holder and the valve besides the packing are marked with identification symbols. The holder 9 is so designed that it fits into in the valve only in one way.

The holders for heart valves are relatively simple objects, generally manufactured of plastics. The holder is manufactured in one or two parts and concerning the mechanical valve, the holder fits exactly in the opening of the valve, while the holders for biological valves are sutured onto one or other side of the valve.

Conventional holders for the double bladed heart valves face the problem that they can be mounted from both sides of the valve. When one handles an aortic valve, the holder must be placed on the opening side of the valve, while a mitral valve holder must be placed on the valve closing side. If the valve is turned wrong in the heart, the passage is closed and the heart cannot pump. If the error is detected by the surgeon, the valve must be removed to the correct

position, other wise the patient cannot survive the operation.

To prevent an aortic valve holder being mounted from the wrong side the safety means 20, according to the present invention, is developed so that it only fits from the opening side. Although such holders are only manufactured in one colour, the mistake can be eliminated with a considerable extent. To prevent a mitral valve holder to be mounted from the wrong side in a similar method the safety means 20 is developed on the mitral holder so that the holder can only be mounted from the closing side.

Although the labels of different types are put on the packing or on the valve itself, they are not any guarantees that correct valve size is used. According to the invention, the size of the valve ring is decided by the holder, which besides having a visible number infused in the plastic at the production, it also has same colour marking as the prosthesis tester.

To further ensure that a wrong size indication on the valve is not mounted on the holder, a safety ring 21 is placed over the valve cuff 13 of the heart valve, as it is suggested in fig. 5. The safety ring 21 is made of two halves 22, 23 which are held together by a suture 24 and are removed before the valve is sutured firmly on the heart, while the holder 9 itself is removed after the valve has been placed in its end position in the heart.

The safety ring 21 is designed to fit only to one size of

the holder. For example, by means of varying length L of a peripheral recess 25 and a corresponding projecting part 26 in the safety ring 21, where the length "L" is different for different valve sizes, the confusions can be avoided. If the holder is made in such a way, a larger safety ring 21 cannot fit in the recess 25. Mounting a smaller ring in the holder is not also possible, since the outer dimension of the valve is larger than the safety ring, which consequently will not fit across the valve cuff 13. Furthermore, on the holder as well as on the safety ring a dimension number is infused in plastic and they are of same colour.

As it appears from Fig. 5, the safety ring 21 has an internal recess 27, the form of which fits the valve cuff 13. Since cuffs in mitral and aortic valves are different, usually with a larger cuff in the mitral valves and with different inclination profiles on the side, which is turned against the heart, the safety ring will be a guarantee that right type of valve is mounted on the holder. Thus, with this system a mitral valve cannot be mounted in an aortic holder by mistake and an aortic valve cannot be mounted in a mitral holder, which is the case with present existent systems.

If the holder is manufactured in this way, this guarantees that only valves of the same size can be mounted on the holder, which is not the case with present existing systems. This is specially important, since the size of the valve, which is chosen by the surgeon, is usually critical and the size is not excellent on the valve itself, but generally only on the packing.

The invention is very simple and costs for the change of the holder and the outward ring is least compared with the problems that a simple mistake should cost (and mistakes have been occurring more than once). The new holders will not negatively effect the valves in any other way than that until now.

Generally, artificial heart valves are supplied in transportation container 28 with the holder mounted in the valve. The holder has a double function, partly during the transportation which fixes the valve, and partly it is usable during the suture in the heart as a practical little lever.

As it appears from fig. 4 the shaft 29 of the holder is equipped with one or more outer fitting elements, which in this embodiment consists of peripheral recesses 30 and bars 31, which have different width for every desired type and size of the holders. The transportation container 28 at the production is provided with corresponding recesses 32 and bars 33. By varying the size and the number of the recesses and the distance between these, endless combinations are obtained, which allow only one special type of valve holder fit the container. Tanks to that, the valve holder cannot simply fit in the container without being of correct type, the confusion is prevented already at the packaging at the factory before distribution of the possible wrongly indicated product.

The recesses 30 and the ledges 31 can also be used for identification of the holder in the production, if the tool

handling the product is provided with corresponding details, in case some one so desires.

Also, the safety ring 21 can be provided with the fitting element, which is developed so that only correct type of valve can fit into the container 28, which is exemplified in fig. 5.

By providing the valve holder with these simple fitting elements the risk of a valve being placed in a wrong container is eliminated, assuming that the valve holder from the beginning is constructed so that only a right valve can be mounted on the holder.

Due to different causes a holder or a part thereof may be left in the area of the operation and cause serious problems. To be able to discover that some strange object of mentioned type is left in the body after the operation, preferably, the holder is made of a material which becomes visible by x-ray on a x-ray plate or screen. Another possibility is to add micro particles, having enough density that it can be detected by means of x-ray, to the plastic material during the manufacturing the holder. A third possibility is that to the exterior of the holder apply (infuse) small plates or the like, which become visible by means of x-ray. It is also possible to "mark" the holder using radioactivity, so that it can be detected if it should be left in the body.

When changing the heart valve it can also be desired to change the part of the aorta that is directly connected to

the valve. Fig. 6 shows a holder specially constructed for this purpose, which is provided with an extended handle portion 19 that is some how longer than the aortic prosthesis 34.

In certain cases biological heart valves are used, which require special holders, as shown in fig. 7, which comprises a base plate 35 with peripheral flanges 36 to which the biological valve 37 is rigidly sewn with some stitches. In same way, in other embodiments at the base plate 35 is provided safety means 20, which is provided to extend into the valve. At the handle portion 19, for instance there is provided fitting elements 30 and 31, for cooperation with corresponding fitting elements at the transportation container.

CLAIMS

1. A holder (9) for artificial heart valves (10-13), of the type that is firmly fixed to the valve, which is intended to be removed first after that the valve is correctly placed or operated inside, by braking a transportation safety (17), after which the holder can be removed,
characterized therein,
that the holder (9) is equipped with safety means (20) extending into the heart valve (10-13), which is formed to fit only into a certain definite valve type, valve position and valve size.

2. A holder according to claim 1,
characterized therein,
that it consists of two parts (9), assembled to each other through a joint (16), and one of which parts (19) includes a handle, which handle portion is provided with said safety means (20).

3. A holder according to claim 2,
characterized therein,
that said second part (18) is firmly fixed to the handle portion (19) by means of a transportation safety (17), preferably in form of suture holding said parts.

4. A holder according to claim 1, 2 or 3,
characterized therein,
that a safety ring (21) is detachably mounted at the holder (9) surrounding the exterior of the heart valve periphery, said ring being arranged by a recess (27) corresponding to

the shape of the heart valve periphrasis part (13).

5. A holder according to claim 4,
characterized therein,
that the safety ring (21) and the holder is provided with at least one respective recess (25) and to the recess corresponding projecting part (26), and
that the heart valves with different sizes are provided with recesses (25) and parts (26) of different length.

6. A holder according to claim 1,
characterized therein,
that the holder of different type and/or size is marked by means of different colours.

7. A holder according to claim 1 or 4,
characterized therein,
that the holder (9) and/or the safety ring (21) is provided with a first fitting element (32, 33),
that a transportation container (28) intended for the holder (9) and the heart valve (10-13) is provided with corresponding second fitting element with complementary form, and
that the fitting elements (30, 31) are formed to fit only certain defined valve type and size.

8. A holder according to claim 7,
characterized therein,
that the first fitting elements consist of recesses (30) and bars (31), provided at the shaft (29) of the holder (9) and/or at a safety ring (21) connectable to the holder and

that the second fitting element consists of corresponding recesses (32) and bars (33) provided in the transportation container (28), which are so formed that the fitting element of the holder (9) is connectable to the fitting element of the container, so that the holder with a mounted heart valve is non-mistakably fixed in the container.

9. A holder according to any or some of proceeding claims, characterized therein,
that the holder (9) is produced of a material and contains materials respectively, which are detectable through X-ray or through emitting detectable radiation, e.g. radioactive radiation.

10. An operation set for cardiac surgery according to any or some proceeding claims, including an artificial or biological heart valve, a valve holder, a prosthesis size tester, and a transportation container, associated regarding size,
characterized therein,
that the heart valve, the valve holder the prosthesis tester are provided with same colour and/or are marked by symbol.

FIG. 1

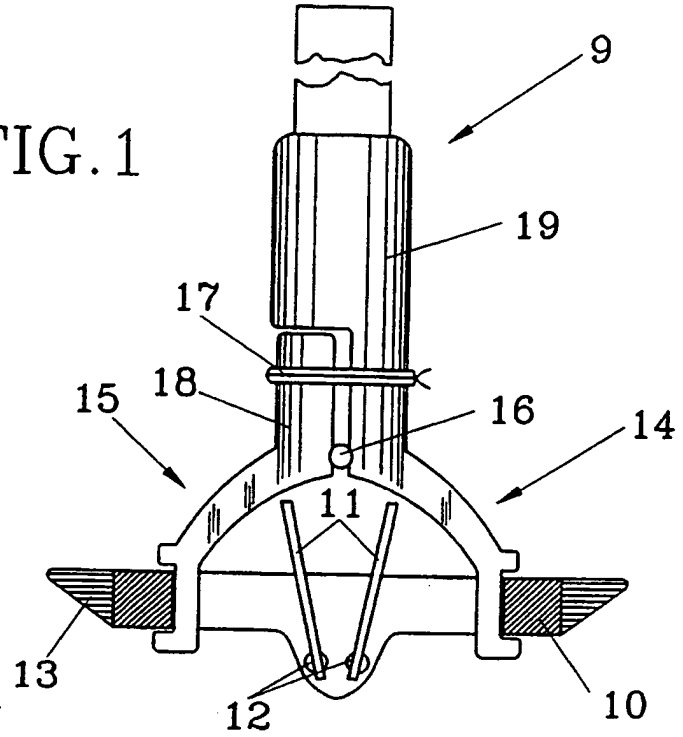


FIG. 2

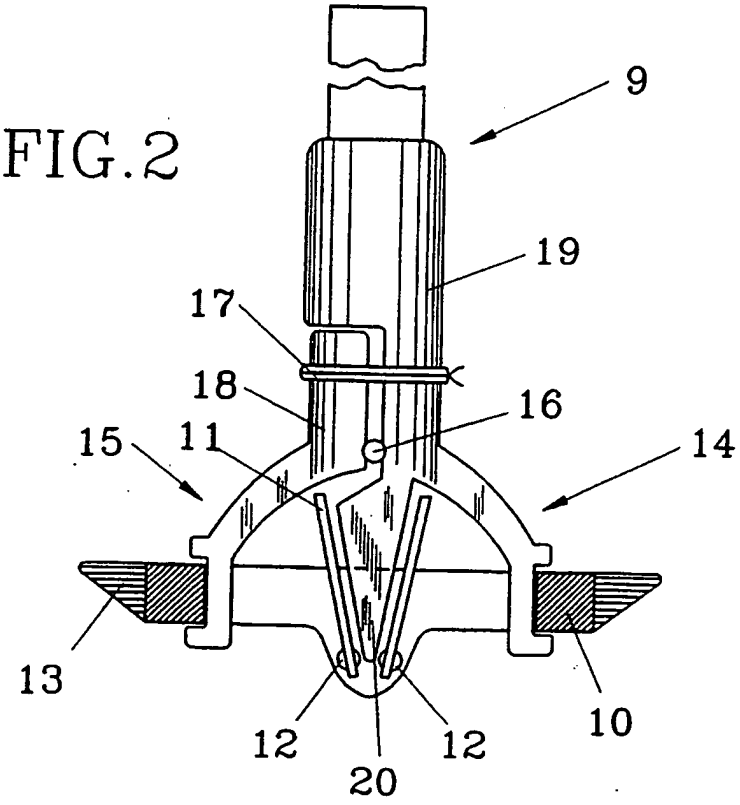


FIG.3

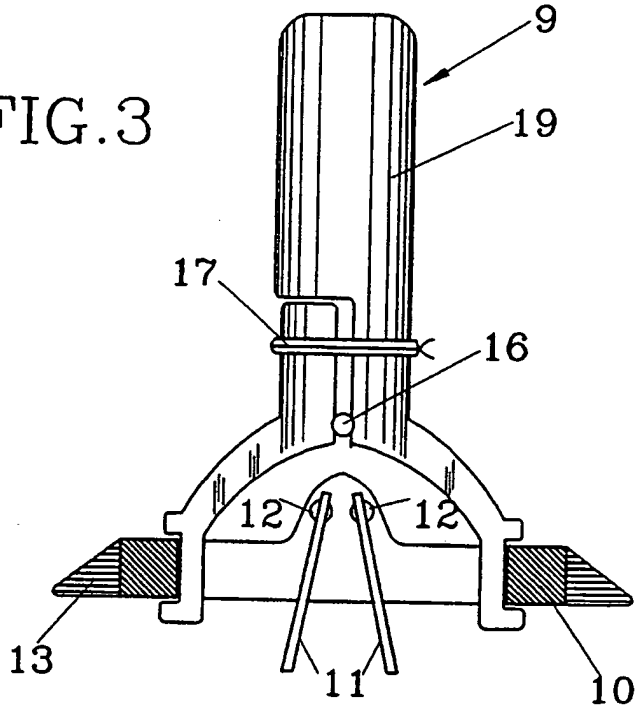


FIG.4

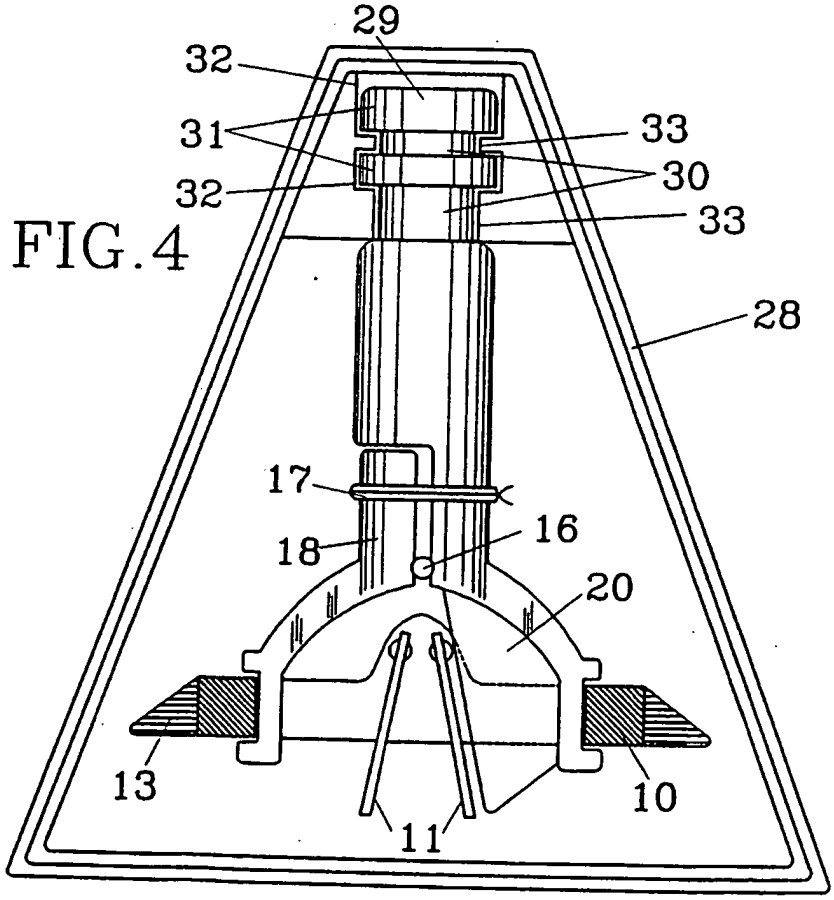


FIG.5

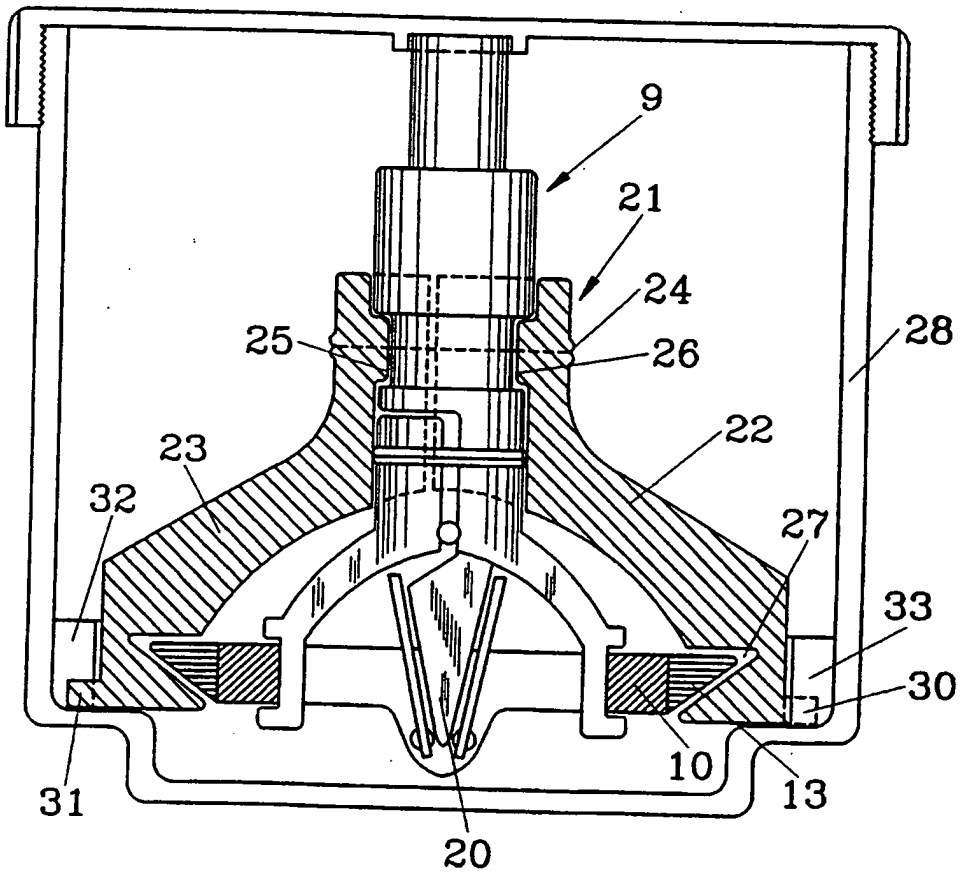


FIG.6

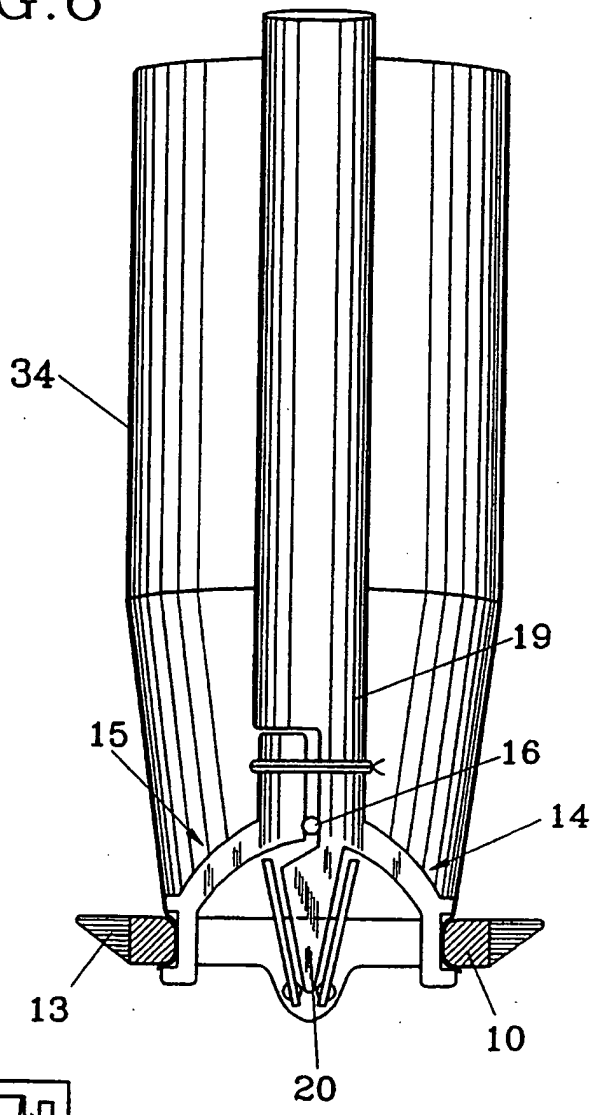
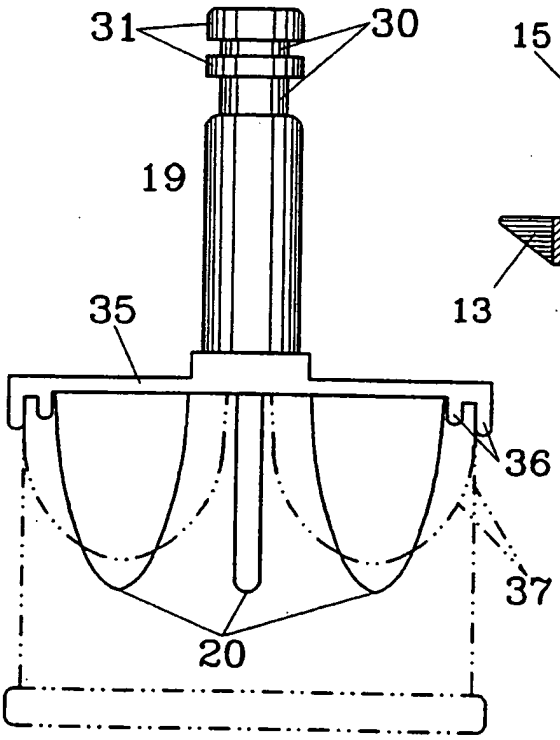


FIG.7



INTERNATIONAL SEARCH REPORT

International application No.
PCT/SE 94/01247

A. CLASSIFICATION OF SUBJECT MATTER

IPC6: A61F 2/24 // A61B 17/00, A61B 19/02
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC6: A61B, A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

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WPI, CLAIMS, EPODOC

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO, A1, 9212688 (ZAVOD ELEKTRONMASH), 6 August 1992 (06.08.92), figures 1-2, abstract --	1
A	GB, A, 2181057 (BLAGOVESCHENSKY GOSUDARSTVENNY MEDITSINSKY INSTITUT ET AL), 15 April 1987 (15.04.87), page 2, line 54 - line 81, figures 1,3 --	1-2
A	US, A, 3409013 (H. BERRY), 5 November 1968 (05.11.68), column 2, line 21 - line 45, figures 4-5 --	1-2

[X] Further documents are listed in the continuation of Box C. [X] See patent family annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
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INTERNATIONAL SEARCH REPORT

International application No.
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C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US, A, 3828787 (LAWRENCE ANDERSON ET AL), 13 August 1974 (13.08.74), column 1, line 20 - line 47, figures 4,9	1
A	US, A, 5201880 (JOHN T.M. WRIGHT ET AL), 13 April 1993 (13.04.93), column 7, line 4 - line 42, figure 2	6,9-10
A	US, A, 5236450 (PETERS T. SCOTT), 17 August 1993 (17.08.93), column 5, line 6 - line 37, figures 3-5	1-3,10

INTERNATIONAL SEARCH REPORT

Information on patent family members

25/02/95

International application No.
PCT/SE 94/01247

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		FR-A,B- 2588747	24/04/87
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US-A- 3409013	05/11/68	NONE	
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